

Exhibit A



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June 10, 2021

Via E-Mail Only

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**Re: In re Valsartan, Losartan, and Irbesartan Liability Litigation
Case No. 1:19-md-02875-RBK-KMW**

Counsel:

Plaintiffs write to address the ongoing unresolved deficiencies in the productions of Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. (“Hetero”). Despite the numerous meet and confers in the past months, and Hetero’s ongoing productions, there are still many deficiencies yet to be resolved.

A. Discovery Issues Related to Chromatograms and Process Development

(1) chromatograms for

a) the NDMA testing that was done by Analys labs – we have reviewed the bates numbers identified by Nakul previously, but cannot locate the chromatograms for the batches sold in the United States that were identified as being contaminated with NDMA. For example, the API batch number VT18040002 testing result is located at Bates HLL206477 showing a contamination with NDMA of 5.16ppm, however, there is no associated chromatogram or other backup to that result. The same issue exists for finished dose testing, for example, finished dose lot number VLS18049 has a testing result at HETERO_USA000025242 but there is no associated chromatogram or backup to that result. The lack of chromatograms and backup is of particular issue here given the FDA’s 483 notice to Analys labs regarding the reliability of its

data, that Hetero failed to retest its products after the 483 notice, and the limited range of ppm for which the Analys labs tests were deemed to be reliable;

b) the in-house GC residual solvent testing that Hetero did during batch manufacturing – we cannot locate any of the underlying chromatograms, only the certificates of analysis. It is my understanding that every other manufacturer other than Hetero has produced the underlying chromatograms that were done as part of the batch manufacturing process.

(2) The process development documents, including but not limited to any genotoxic analysis performed, with regard to the development of Process III from Process I. There appears to be no possibility that Process III was developed with no written documentation regarding how it was developed, the experimentation done to develop it, the theoretical analysis done to develop it, etc. Plaintiffs have also requested all documentation regarding any genotoxic analysis done during the Process III development phase other than the information contained in the DMF and sANDA. Hetero has now produced one document that discusses the optimization of Process III, but still has produced no documents evidencing how Process III was developed to begin with, nor any documents evidencing what, if any, analysis was done regarding analysis for genotoxic impurities.

On May 26, 2021, Dr. Kumar testified that the potential genotoxic impurity analysis performed by Hetero during the development of Valsartan Process III was done using a software called Derek. Defendants have now produced 12 documents from Derek. These documents are produced completely without context, and do not show how they were used, what they were used for, nor any communications with regard to these documents. This is unacceptable. Please confirm if Hetero's position is going to be that these isolated documents represent the sum total

of all genotoxic analysis done during the Process III development and manufacturing phases up until July 2018.

Further, with regard to the Derek system, and any other systems that may have been used to conduct potential impurity analysis of Valsartan Processes I-III, Plaintiffs requested that Hetero provide (or the extent it believed it already produced, to identify by bates number) all results related to Valsartan Processes I-III, all SOPs or other procedures documenting the use of Derek and/or other such software, all communications regarding the results of any such analysis of Valsartan Processes I-III, details of the software(s) and versions used during the 2012-2019 time frame, and all software manuals and documentation regarding Derek and/or other such software. As noted above, Hetero has produced only 12 documents regarding Derek output, and none of the other requested materials.

B. Discovery Issues Specifically Related to the Deposition of Bandaru (“B.V. Rama Rao”) Venkata Ramarao

The following documents identified during the deposition of the first Hetero 30(b)(6) witness, Bandaru (“B.V. Rama Rao”) Venkata Ramarao, on April 29 and 30, 2021, continue not to be produced nor identified by Hetero as not available. These documents were requested as the deposition proceeded, and after. Plaintiffs also asked Hetero to identify the bates numbers for any documents it contends it produced but have not received any such identification. The list is as follows:

- a. Quality Agreements between Unit 1 and Unit 5, except for the July/August 2019 Technical Agreement.
- b. All change notification(s) from Unit 1 to Unit 5 with regard to the process changes in the manufacturing process for valsartan (from 1 to 2, and 2 to 3), and the Unit 5 responses and ultimate sign off. This does not include Rupa Rani Pendyala’s email, dated December 10, 2015, requesting documents for the new

VT series nor Krishnaveni B's email, dated April 20, 2015, providing specifications for the new VSR series.

- c. Any documentation of a Unit 5 risk assessment with regard to any of the process changes prior to the recall in July of 2018.
- d. Any documentation of a Unit 1 risk assessment with regard to any of the process changes prior to the recall in July of 2018.
- e. Confirmation that the TRIMS application/database and training materials have been produced and identification of the information therein with regard to all custodians.
- f. Confirmation that the QAMS application/database has been produced, and the emails between Unit 1 and Unit 5 with regard to the change notification(s).
- g. The Risk Assessment Protocol(s) for Unit 5 and Unit 1 prior to the recall.
- h. The Unit 5 Change Control Protocol(s), and evaluation(s) of the changes in the manufacturing process.
- i. Except for the employee training history for Bandaru Venkata Ramarao and N.G. Panchakshari, training documents on the TRIMS application/database for all other custodians.
- j. Any Unit 5 protocol that addresses genotoxic impurities, as well as any such protocol at Unit 1, in addition to the one protocol, method verification for genotoxic impurities protocol, identified by Mr. Ramarao during his deposition.
- k. Except for Unit 1's response letter dated August 29, 2019, Unit 1's response to Unit 5's Audit Report identified during Mr. Ramarao's deposition, and any

further back and forth. All reports of audits Unit 5 conducted of Unit 1, except for the November 2018 Audit Report, including all responses back and forth as well.

C. Discovery Issues Specifically Related to the Deposition of Dr. Venkataramana Madireddy

The cover pages, table of contents, and, specifically, any portion of the notebook that would identify when it was first “issued” as testified to by Dr. Venkataramana have yet to be produced for all nitrosamine impurities that were created in-house by Hetero.

D. General Production Deficiencies

Plaintiffs identified the following deficiencies in Hetero’s production which remain to be produced or identified as not available:

a. Annual Product Reviews for U.S. Market

- i. Final versions of the annual products reviews of 40mg, 80mg, 160mg, and 320mg from 2010-2013 and 2019 for Unit 5

b. Unit-IX Reports relating to Valsartan. Your letter dated May 20, 2021, provides that the following documents were produced in the HLL19 production, however we have been unable to locate them. Please identify the bates ranges for each of the following:

- i. CR-VN-PD-16-001
- ii. CR-EDQC-18-0021
- iii. CR-EDQC-17-0083

c. Research and Development

- i. All Master SOP Indexes/Document Indexes for R&D, except for R&D- SOP/003 – R&D-SOP/005

d. Document Indexes: Quality Assurance (Unit 1)

- i. QA-SOP/000, QA-SOP/004, QA-SOP/012 – QA-SOP/015, QA-SOP/019– QA-SOP/023

e. Standard Operating Procedures: Quality Assurance (Unit 1)

- i. All final versions of SOP No. 20-001 – 20-003
- ii. All final versions of SOP No. 20-004, except for 20-004-06
- iii. All final versions of SOP No. 20-005– 20-006
- iv. All final versions of SOP No. 20-007, except for 20-007-03
- v. All final versions of SOP No. 20-008, except for 20-008-05
- vi. All final versions of SOP No. 20-009
- vii. All final versions of SOP No. 20-010, except for 20-010-08
- viii. All final versions of SOP No. 20-011, except for 20-011-03
- ix. All final versions of SOP No. 20-012– 20-017
- x. All final versions of SOP No. 20-018, except for 20-018-01
- xi. All final versions of SOP No. 20-019, except for 20-019-01
- xii. All final versions of SOP No. 20-020, except for 20-020-02
- xiii. All final versions of SOP No. 20-021, except for 20-021-01
- xiv. All final versions of SOP No. 20-022, except for 20-022-01
- xv. All final versions of SOP No. 20-023, except for 20-023-01
- xvi. All final versions of SOP No. 20-024, except for 20-024-01
- xvii. All final versions of SOP No. 20-025
- xviii. All final versions of SOP No. 20-027, except for 20-027-01
- xix. All final versions of SOP No. 20-028, except for 20-28-01
- xx. All final versions of SOP No. 20-029, except for 20-029-01

- f. *Standard Operating Procedures: Quality Assurance (Unit V)* - Please confirm that the following versions are latest versions:
- i. QA041-07
 - ii. QA056-03 and
 - iii. QA102-01
- g. *Master SOP Indexes: Analytical Development*
- i. Please confirm that the only Master SOP Indexes/Document Indexes for Analytical Development are Version 00 – 02
- h. *Document Indexes: Corporate Quality Assurance*
- i. Document Indexes: CQA-SOP/067 - CQA-SOP/089
- i. *Standard Operating Procedures: Corporate Quality Assurance*
- i. Please provide the bates numbers for the final version of CAQ005-01, we can only locate a draft version, and
 - ii. Please provide bates numbers for all versions of CQA020. We cannot locate any version of CQA020.
- j. *Standard Operating Procedures: Quality Control*
- i. We are missing the following versions:
 1. Need the final version of QC021-03.
 2. Need the final version of QC023-01.
 - ii. Please confirm the SOP is the latest version.
 1. QC009-11
- k. *Document Indexes for Additional Departments*
- i. Warehouse

1. WH-SOP/02, WH-SOP/11–WH-SOP/12, WH-SOP/20–WH-SOP/34, WH-SOP/38, and WH-SOP/43

- ii. Engineering

1. EN-SOP/000–EN-SOP/009, EN-SOP/011–EN-SOP/012, EN-SOP/016–EN-SOP/017, EN-SOP/031–EN-SOP/032, EN-SOP/039–EN-SOP/042, EN-SOP/045–EN-SOP/046.

- iii. Microbiology

1. MB-SOP/000, MB-SOP/002, MB-SOP/005, MB-SOP/014, MB-SOP/016, MB-SOP/026, MB-SOP/031, MB-SOP/033, MB-SOP/041, MB-SOP/045, MB-SOP/053, MB-SOP/054, MB-SOP/057

- iv. Production

1. PD-SOP/01, PD-SOP/02, PD-SOP/09, PD-SOP/10, PD-SOP/43, PD-SOP/45–PD-SOP/52, PD-SOP/54, PD-SOP/57, PD-SOP/59, PD-SOP/68

Plaintiffs also requested all documents related to CAPA-VS-069.

All of the above documents remain to be produced or identified as not existing. Further, to the extent that they do not exist, Hetero needs to identify whether they did not exist at all, or whether they have been lost or destroyed, and if lost or destroyed, the date and manner of such loss or destruction.

Given that it is now months past when most these items were first raised with Hetero, that all of these documents should have been produced before by the document discovery cut-off in November, 2020 as they are clearly responsive to Plaintiffs' requests for production, and that these

issues, many of them fundamental, still remain to be cured, Plaintiffs will be requesting that the Court enter an Order prohibiting Hetero from relying on any documents produced after the date of the next discovery conference, that Hetero's witnesses be barred from relying on or referencing any documents, and events covered by such documents, not produced after the date of the next discovery conference, and requesting that an adverse inference be drawn in any future proceedings from Hetero's failure to produce the above requested documents.

Best regards,

A handwritten signature in black ink, appearing to read 'Behram V. Parekh', written in a cursive style.

Behram V. Parekh

cc: Plaintiffs' Executive Committee (via e-mail)